

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 126526.3 MM	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IL00/00506	International filing date (day/month/year) 23/08/2000	Priority date (day/month/year) 23/08/1999
International Patent Classification (IPC) or national classification and IPC A61B5/0428		
Applicant SHL TELEMEDICINE INTERNATIONAL LTD. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 19/03/2001	Date of completion of this report 13.11.2001
Name and mailing address of the international preliminary examining authority: <div style="display: flex; align-items: center;"> <div> European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 </div> </div>	Authorized officer Küster, G Telephone No. +49 89 2399 7240



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IL00/00506

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*):

Description, pages:

1-3,6-12	as originally filed	
4	with telefax of	19/03/2001
4a,5	with telefax of	25/09/2001

Claims, No.:

1-13	with telefax of	25/09/2001
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Drawings, sheets:

1/5-5/5	as originally filed
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2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IL00/00506

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☒ the claims, Nos.: 14
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-13
	No:	Claims	none
Inventive step (IS)	Yes:	Claims	1-13
	No:	Claims	none
Industrial applicability (IA)	Yes:	Claims	1-13
	No:	Claims	none

**2. Citations and explanations
see separate sheet**

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents cited in the ISR:

D1: DE-A-36 37 956

D2: GB-A-2 287 882

D3: WO 94 26350 A

It is noted that D1 is a patent family member of US-A-4 763 660 cited on p. 3 l. 15 of the application.

1. The subject-matter of independent **claim 1** meets the requirements of the PCT with respect to novelty (Article 33(2) PCT) and inventive step (Article 33(3) PCT) for the following reasons:

Document D1, which may be regarded as closest prior art, discloses an electrode assembly comprising the features of the preamble of claim 1.

The problem to be solved is to provide a **compact** portable assembly, which the patient may easily carry with him (cf. p. 1 l. 10-12 and p. 2 l. 28 - p. 3 l. 5 of the present application).

The inventive solution to this problem resides in that the flexible support comprises a plurality of foldable sections. By this means the electrode assembly can be folded into a compact unit when not in use, which can easily be carried by the patient (cf. p. 6 l. 20-22 of the present application).

Document D2 discloses an electrode assembly that may be folded and rolled for storage or transportation (claim 2). The electrodes are provided on leads that leave a flexible sheet rather than being constructed on the sheet itself (middle para. of p. 1, claim 1). The leads are enclosed within the flexible sheet for their most part (claim 1), e.g. between two pressed plastic sheets (fig. 3, cf. reference to this figure on p. 2). The electrodes produce electrical contact also with other locations than the patient's chest (fig. 2).

A combination of the features of the foldable sheet described in D2 with the features of the electrode assembly of D1 would not be obvious to the skilled person, since the foldability of the sheet in D2 is not automatically preserved if the electrodes are located on the sheet (as in D1).

Neither of the documents D1 and D2 addresses the problem of providing a compact assembly to be carried by the patient. The assembly described in D2, also described as an "E.C.G. Bodymat" (last para. of p. 1), does not appear suitable for portability and use by the patient himself (fig. 2, cf. also paragraph (b) on p. 2).

Document D3 discloses an electrode assembly for a defibrillator (cf. p. 1 l. 8-10; use with an ECG signaling device is hinted at on p. 9 l. 21-26), where in one embodiment two electrodes are constructed on a flexible, foldable support each (p. 4 l. 22-30, p. 5 l. 22-24, fig. 7). The two electrode supports are folded and placed in a retainer for storage (fig. 3, p. 5 l. 18-24). In an alternative embodiment, two electrodes are constructed on one support (fig. 9, p. 7 l. 13-24), which is wound around a retainer (figs. 11-12, p. 8 l. 6-10). In the first embodiment (cf. fig. 2), a relatively stiff electrode body (45), within which the electrode (44) is disposed, is attached to a flexible substrate (42) made of a polymer with approximately 0.08 mm (3 mils) thickness (p. 4 l. 25-27). In the second embodiment (cf. fig. 10), the electrodes (144) are attached to a flexible substrate (142) preferably formed from 1.6 mm (1/16") closed cell foam (p. 7 l. 14-17). No hint is given as to combine the foldable support of the first embodiment with the electrode arrangement of the second embodiment.

2. **Claims 2-9** are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.
3. **Claims 10-13** relate to an ECG signaling device comprising an electrode assembly according to any one of claims 1-9 and therefore also meet the requirements of the PCT with respect to novelty and inventive step.

INTERNATIONAL SEARCH REPORT

International Application No

PC/7/IL 00/00506

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/0428

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, INSPEC, COMPENDEX

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 287 882 A (LOWRY WILLIAM SHIELDS) 4 October 1995 (1995-10-04) page 2, paragraph "(b)" claim 2	1,2,7,9, 10
A	US 5 029 590 A (ALLAIN JOSEPH L ET AL) 9 July 1991 (1991-07-09) column 5, line 57 -column 6, line 32 column 6, line 57 - line 65	1-3,9, 11,13,14
A	WO 94 26350 A (HEARTSTREAM INC) 24 November 1994 (1994-11-24) page 5, line 18 - line 28 page 6, line 36 -page 7, line 12 page 9, line 21 - line 26 -/--	1-4, 9-11,13, 14

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

6 December 2000

Date of mailing of the international search report

14/12/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer

Knüpling, M

- 4 -

ground inputs to the medical electronic instrument, is precisely determined by virtue of the disposition of the electrodes in the wells. The electrode structure provides contact with a body surface, usually the skin. To facilitate the contact a conductive jelly is used. This conductive jelly is received in the wells. It makes
5 contact with the electrodes. Ribs are provided in the regions between the electrodes, which form a seal at the skin so as to prevent the flow of conductive fluid between electrodes; thus preventing short circuits. The flexibility of the structure provides for comfort and reliable long term attachment and also for maintaining the contact of the electrodes and sealing ribs with the skin as the skin
10 and muscle beneath, flex.

US Patent No. 4,004,578 discloses an expendable electro-cardiograph electrode comprising a thin metallic carrier member coated on the surface to be applied to the skin with an adhesive and having a plurality of metallic contact spikes projecting from the coated surface which spikes are devised to penetrate into
15 the skin. The coated and spiked surface is covered by at least one pull-off foil protecting same together with the spikes against environmental influences. On the carrier member, a transverse upwardly directed flange is provided for attachment to an electrocardiographic apparatus.

US Patent No. 5,305,746 discloses a disposable, pre-gelled, self-prepping
20 electrode having an array or mat of flexile tines which serve to part the high impedance outer layers of skin to expose the low impedance, blood enriched layers without scratching or abrading. The tines are preferably imbedded in a conductive gel layer. In an alternative embodiment, a self prepping layer of flexile tines embedded in gel may be a single disposable self-prepping layer that is mounted
25 over a permanent electrode.

GB 2 287 882 discloses a flexible sheet having ECG connecting leads enclosed within the sheet to a point close to their desired anatomical destination and that can be rolled up for storage. Essentially, this reference teaches a device that eliminates the tangling of wires which is perceived to be a problem with

- 4a -

standard ECG leads, although no specific mention is made that the device disclosed therein is suitable for a 12 lead electrode assembly. In any event, whilst suggestion is made in GB 2 287 882 to direct the ECG leads to a point close to their desired anatomical destination, all that is meant thereby is that the wires constituting the

5 ECG leads protrude from appropriate edges of the electrode support so as to most easily directed to appropriate parts of the body. GB 2 287 882 does not teach a flexible electrode support for supporting on the electrode support itself clinically pre-positioned electrodes in proper spaced relationship for placing directly against a patient's chest so as to produce an electrocardiogram.

10 It thus emerges that the prior art relates to disposable electrodes that are flexible but that the issues of compactness and especially the ability to fold the electrode are not addressed in the prior art.

SUMMARY OF THE INVENTION

15 It is an object of the invention to provide a portable compact electrode assembly for a portable ECG monitor allowing standard twelve-lead ECG measurements to be carried out.

- 5 -

This objective is realized in accordance with a broad aspect of the invention by means of an electrode assembly for a portable ECG signaling device, comprising:

a thin, flexible electrode support supporting a plurality of electrodes at least some of which are constructed on the electrode support in proper spaced relationship for producing electrical contact with respective areas of a patient's chest for producing an electrocardiogram when the electrode assembly is placed directly against the patient's chest;

characterized in that:

the flexible support comprises a plurality of foldable sections, whereby the electrode assembly can be folded into a compact unit prior to or after use.

According to a preferred embodiment, the electrode assembly is coupled to an ECG transmitter embedded with a wallet and having controls accessible from inside the wallet. Such a wallet is provided with pockets for accommodating therein cash, credit cards and so on in known manner so that the patient who carries it is psychologically immune from the uncomfortable thought that anything medical is associated therewith.

In order to allow the patient to relay the ECG signal to a remote monitoring unit, a vocalizing unit may be provided for converting the ECG signal to a representative acoustic signal that can be sent over the telephone to the monitoring unit. Alternatively, the ECG signal may be modulated on to an r.f. carrier signal for direct transmission with the monitoring unit, thus not requiring that the patient be in ready access with a telephone.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

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CLAIMS:

1. An electrode assembly (10) for a portable ECG signaling device, comprising.

5 a thin, flexible electrode support (11) supporting a plurality of electrodes (V1, V2, V3, V4, V5 and V6, LA, RA, LL) at least some of which are constructed on the electrode support in proper spaced relationship for producing electrical contact with respective areas of a patient's chest for producing an electro-

cardiogram when the electrode assembly is placed directly against the patient's chest;

10 characterized in that:

the flexible support (11) comprises a plurality of foldable sections (12, 13, 15), whereby the electrode assembly can be folded into a compact unit prior to or after use.

15 2. The electrode assembly according to Claim 1, being embedded within a wallet (19, 55).

3. The electrode assembly according to Claim 1 or 2, wherein one of the foldable sections (13) is provided with a flap (21) for tucking into a slot (20) in another one (12) of said sections, whereby the electrode assembly can be folded into a self-contained compact unit prior to use.

20 4. The electrode assembly according to any one of the preceding claims, wherein there is joined to at least one of the foldable sections (12) a serpentine strip (14) supporting thereon one of said electrodes (RA).

5. The electrode assembly according to any one of the preceding Claims, wherein the electrodes are formed by a screen-printing technique.

25 6. The electrode assembly according to any one of the preceding Claims, including a plurality of electrode arrays dimensioned for different sized patients.

7. The electrode assembly according to Claim 6, wherein some of said electrode arrays are for male use exclusively and others are for female use exclusively.

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8. The electrode assembly according to any one of the preceding claims, further including a connector (22) for removably connecting to the electrode assembly an electronic circuit.

9. The electrode assembly according to Claim 8, being adapted for one time use.

10. An ECG signaling device (30, 50) comprising an electrode assembly according to any one of the preceding Claims.

11. The device according to Claim 10, including a vocalizing unit (35, 36) for producing an acoustic signal representative of the patient's ECG.

12. The device according to Claim 10, including digital circuitry (41) for producing a digital signal representative of the patient's ECG.

13. The device according to any one of Claims 10 to 12, being integrally embedded within a wallet (19, 55).

- 5 -

SUMMARY OF THE INVENTION

It is an object of the invention to provide a portable compact electrode assembly for a portable ECG monitor allowing standard twelve-lead ECG measurements to be carried out.

5 This objective is realized in accordance with a broad aspect of the invention by means of an electrode assembly for a portable ECG signaling device, comprising:

a thin, flexible electrode support supporting thereon a plurality of electrodes in spaced relationship;

10 CHARACTERIZED IN THAT:

the electrodes are configured for producing a twelve-lead electrocardiogram, and

the electrode assembly is foldable into a compact assembly when not in use.

15 According to a preferred embodiment, the electrode assembly is coupled to an ECG transmitter embedded with a wallet and having controls accessible from inside the wallet. Such a wallet is provided with pockets for accommodating therein cash, credit cards and so on in known manner so that the patient who carries it is psychologically immune from the uncomfortable thought that anything medical is associated therewith.

20 In order to allow the patient to relay the ECG signal to a remote monitoring unit, a vocalizing unit may be provided for converting the ECG signal to a representative acoustic signal that can be sent over the telephone to the monitoring unit. Alternatively, the ECG signal may be modulated on to an r.f. carrier signal for direct transmission with the monitoring unit, thus not requiring that the patient be in
25 ready access with a telephone.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

- 4 -

ground inputs to the medical electronic instrument, is precisely determined by virtue of the disposition of the electrodes in the wells. The electrode structure provides contact with a body surface, usually the skin. To facilitate the contact a conductive jelly is used. This conductive jelly is received in the wells. It makes
5 contact with the electrodes. Ribs are provided in the regions between the electrodes, which form a seal at the skin so as to prevent the flow of conductive fluid between electrodes; thus preventing short circuits. The flexibility of the structure provides for comfort and reliable long term attachment and also for maintaining the contact of the electrodes and sealing ribs with the skin as the skin
10 and muscle beneath, flex.

US Patent No. 4,004,578 discloses an expendable electro-cardiograph electrode comprising a thin metallic carrier member coated on the surface to be applied to the skin with an adhesive and having a plurality of metallic contact spikes projecting from the coated surface which spikes are devised to penetrate into
15 the skin. The coated and spiked surface is covered by at least one pull-off foil protecting same together with the spikes against environmental influences. On the carrier member, a transverse upwardly directed flange is provided for attachment to an electrocardiographic apparatus.

US Patent No. 5,305,746 discloses a disposable, pre-gelled, self-prepping
20 electrode having an array or mat of flexible tines which serve to part the high impedance outer layers of skin to expose the low impedance, blood enriched layers without scratching or abrading. The tines are preferably imbedded in a conductive gel layer. In an alternative embodiment, a self prepping layer of flexible tines embedded in gel may be a single disposable self-prepping layer that is mounted
25 over a permanent electrode.

It thus emerges that the prior art relates to disposable electrodes that are flexible but that the issues of compactness and especially the ability to fold the electrode are not addressed in the prior art.

- 13 -

CLAIMS:

1. An electrode assembly (10) for a portable ECG signaling device, comprising.

a thin, flexible electrode support (11) supporting thereon a plurality of electrodes in spaced relationship;

CHARACTERIZED IN THAT:

the electrodes (V_1 , V_2 , V_3 , V_4 , V_5 and V_6 , LA, RA, LL) are configured for producing a twelve-lead electrocardiogram, and

the electrode assembly is foldable into a compact assembly when not in use.

2. The electrode assembly according to Claim 1, being a self-contained unit.

3. The electrode assembly according to Claim 1, being embedded within a wallet (19, 55).

4. The electrode assembly according to any one of Claims 1 to 3, wherein the flexible support (11) comprises a plurality of foldable sections (12, 13, 15), one of which (13) is provided with a flap (21) for tucking into a slot (20) in another one (12) of said sections, whereby the electrode assembly can be folded into a self-contained compact unit prior to use.

5. The electrode assembly according to Claim 4, wherein there is joined to at least one of the foldable sections (12) a serpentine strip (14) supporting thereon one of said electrodes (RA).

6. The electrode assembly according to any one of the preceding Claims, wherein the electrodes are formed by a screen-printing technique.

7. The electrode assembly according to any one of the preceding Claims, including a plurality of electrode arrays dimensioned for different sized patients.

8. The electrode assembly according to Claim 7, wherein some of said electrode arrays are for male use exclusively and others are for female use exclusively.

- 14 -

9. The electrode assembly according to any one of the preceding claims, further including a connector (22) for removably connecting to the electrode assembly an electronic circuit.
10. The electrode assembly according to Claim 9, being adapted for one time use.
11. An ECG signaling device (30, 50) comprising an electrode assembly according to any one of the preceding Claims.
12. The device according to Claim 11, including a vocalizing unit (35, 36) for producing an acoustic signal representative of the patient's ECG.
- 10 13. The device according to Claim 11, including digital circuitry (41) for producing a digital signal representative of the patient's ECG.
14. The device according to Claim 11 or 12, being integrally embedded within a wallet (19, 55).

- 15 -

AMENDED CLAIMS

[received by the International Bureau on 10 January 2001 (10.01.01);
original claim 1 amended; remaining claims unchanged (1 page)]

1. An electrode assembly (10) for a portable ECG signaling device, comprising.

a thin, flexible electrode support (11) supporting a plurality of electrodes
(V1, V2, V3, V4, V5 and V6, LA, RA, LL);
characterized in that:

at least some of the electrodes (V1, V2, V3, V4, V5 and V6) are
constructed on the electrode support in proper spaced relationship for producing
electrical contact with respective areas of a patient's chest for producing an electro-
cardiogram when the electrode assembly is placed directly against the patient's
chest.

2. The electrode assembly according to Claim 1, being a self-contained unit.

3. The electrode assembly according to Claim 1, being embedded within a
wallet (19, 55).

4. The electrode assembly according to any one of Claims 1 to 3, wherein the
flexible support (11) comprises a plurality of foldable sections (12, 13, 15), one of
which (13) is provided with a flap (21) for tucking into a slot (20) in another one
(12) of said sections, whereby the electrode assembly can be folded into a self-
contained compact unit prior to use.

5. The electrode assembly according to any one of the preceding claims,
wherein there is joined to at least one of the foldable sections (12) a serpentine strip
(14) supporting thereon one of said electrodes (RA).

6. The electrode assembly according to any one of the preceding Claims,
wherein the electrodes are formed by a screen-printing technique.

7. The electrode assembly according to any one of the preceding Claims,
including a plurality of electrode arrays dimensioned for different sized patients.

8. The electrode assembly according to Claim 7, wherein some of said
electrode arrays are for male use exclusively and others are for female use
exclusively.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 126526.3 MM	FOR FURTHER ACTION		see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/IL 00/ 00506	International filing date (day/month/year) 23/08/2000	(Earliest) Priority Date (day/month/year) 23/08/1999	
Applicant SHL TELEMEDICINE INTERNATIONAL LTD. et al.			

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

1
☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IL 00/00506

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/0428

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, INSPEC, COMPENDEX

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 287 882 A (LOWRY WILLIAM SHIELDS) 4 October 1995 (1995-10-04) page 2, paragraph "(b)" claim 2	1,2,7,9, 10
A	US 5 029 590 A (ALLAIN JOSEPH L ET AL) 9 July 1991 (1991-07-09) column 5, line 57 -column 6, line 32 column 6, line 57 - line 65	1-3,9, 11,13,14
A	WO 94 26350 A (HEARTSTREAM INC) 24 November 1994 (1994-11-24) page 5, line 18 - line 28 page 6, line 36 -page 7, line 12 page 9, line 21 - line 26 --- -/--	1-4, 9-11,13, 14

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- * & * document member of the same patent family

Date of the actual completion of the international search

6 December 2000

Date of mailing of the international search report

14/12/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
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Fax: (+31-70) 340-3016

Authorized officer

Knüpling, M

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IL 00/00506

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>DE 36 37 956 A (CHERNE IND INC) 11 June 1987 (1987-06-11) column 7, line 37 - line 45 column 11, line 11 - line 34 column 12, line 27 - line 33 column 15, line 31 - line 35 -----</p>	1,2,6-11

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IL 00/00506

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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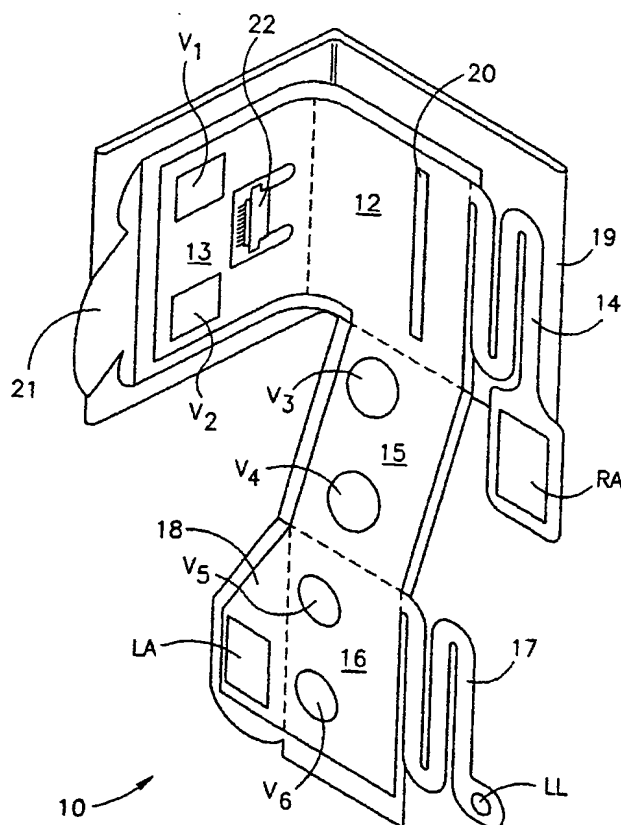
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[Continued on next page]

(54) Title: **COMPACT ELECTRODE ASSEMBLY FOR A PORTABLE ECG SIGNALING DEVICE**

(57) Abstract: An electrode assembly (10) for a portable ECG signaling device, comprises a thin, flexible electrode support (11) supporting thereon a plurality of electrodes in spaced relationship. The electrodes (V₁, V₂, V₃, V₄, V₅ and V₆, LA, RA, LL) are configured for producing a twelve-lead electrocardiogram, and the electrode assembly is foldable into a compact assembly when not in use.



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Compact electrode assembly for a portable ECG signaling device

FIELD OF THE INVENTION

This invention relates to a portable ECG signaling device.

BACKGROUND OF THE INVENTION

Patients having a history of medical ailments not infrequently subscribe to a medical monitoring service on an ambulatory basis. Upon effecting communication with a monitoring unit, the patient is frequently required to undertake an interactive dialog with medical personnel at the monitoring unit so as to enable the medical personnel to diagnose the patient's medical symptoms. Since many of those who are particularly at risk suffer from heart-disease, an ECG is usually one of the first tests which should be carried out. To this end, much effort has been directed to the provision of portable instruments for allowing a patient to carry out an ECG on himself. At their most rudimentary, such instruments comprises a pair of electrodes, which are held against a patient's body, usually near his chest to detect an electrical voltage indicative of the electrical activity of the heart. The resulting current waveform response permits partial determination of the patient's cardiac health. A more detailed determination may be realized by using more than two electrodes and portable devices are known having, for example, ten electrodes mounted on a common carrier and amenable to placement on a patient's chest area by the patient with minimum effort.

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US Patent No. 5,339,823 (Reinhold, Jr.) discloses a method and device for obtaining electrical heart activity of an individual in a form capable of producing a twelve-lead electrocardiogram of an individual. The device includes a portable electrode support having an array of six non-adhesive precordial electrodes fixed thereon at predetermined positions within the array which correspond with the Wilson precordial leads for the individual. The device also includes a right arm electrode, a left arm electrode, a left leg electrode and circuitry for converting the electrical heart activity of the individual obtained by said electrodes into a form capable of producing a twelve-lead electrocardiogram. The method includes the steps of applying the left leg, left arm and right arm electrode to the skin of the individual at locations such that the circuitry can be electrically operable to obtain leads I, II, III, AVR, AVL, and AVF therefrom. Human pressure is applied to engage the array of six precordial electrodes with the skin of the chest of the individual in an operative relation, and circuitry is operated for a time sufficient to obtain electrical heart activity of the individual in a form capable of producing an electrocardiogram.

It will be appreciated that no less important than the technical suitability of such ECG transmitters, is that they must be instantly accessible in a moment of crisis. In the first instance, the required accessibility can only be realized by a portable device. However, experience indicates that this in itself is often not enough. Most people find it difficult to function and to preserve their mental health if they live in constant fear of their mortality. Particularly, those who have a history of heart disease or other serious illness can do without constant reminders that they might need to perform an instant ECG in the street or elsewhere remote from hospital or home. As a result, there are many who consign the thought to their subconscious and it is then but a small step to relegating it to their unconscious altogether.

Such a likelihood would be reduced if the ECG transmitter were not only portable but were so disguised as to be indistinguishable from an everyday item

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which, in any case, the patient would carry on his or her person. Our co-pending International publication no. WO 99/45516 discloses fixedly embedding the ECG electrodes within a wallet containing a microphone, transceiver and processing circuit. However, such an arrangement is limited in size by virtue of the compactness of the wallet, which must be preserved. This requires, in practice, that only two ECG leads are provided, these being sewn into the inside fabric of the wallet and militates against the provision of a full ECG monitoring capability requiring an array of displaced electrodes spanning a patient's chest area.

US Patent No. 5,724,984 discloses a multi-segment ECG electrode including a flexible basepad, a central segment defined on a surface of the basepad, and exterior segments defined on the surface of the basepad. The exterior segments may be sized, shaped and positioned relative to the central segment so that an average position of the exterior segments approximates a position of the central segment.

US Patent No. 4,763,660 discloses a flexible and disposable electrode belt device for receiving and transmitting electric current or voltage for use on the body of a patient. The belt has a unitary layered body structure that is releasably secured to the patient. The belt device body structure has a terminal end that is connectable for communication with medical therapeutic and diagnostic apparatus. The layered body structure further includes a plurality of flexible non-conductive and conductive layers, a conductive network having electrode contact areas at predetermined positions and conductive adhesive members to removably hold the device to a patient and to, thereby, transfer electrical signals between predetermined patient body locations and the medical therapeutic and diagnostic apparatus.

US Patent No. 4,082,087 discloses a body contact electrode structure for deriving electrical signals due to physiological activity, comprising a thin, flexible body of non-conductive material having one or more wells therein. A flexible conductive member which provides an electrode is disposed at the bottom of each well. The spacing between a plurality of electrodes, which can provide bipolar and

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ground inputs to the medical electronic instrument, is precisely determined by virtue of the disposition of the electrodes in the wells. The electrode structure provides contact with a body surface, usually the skin. To facilitate the contact a conductive jelly is used. This conductive jelly is received in the wells. It makes
5 contact with the electrodes. Ribs are provided in the regions between the electrodes, which form a seal at the skin so as to prevent the flow of conductive fluid between electrodes; thus preventing short circuits. The flexibility of the structure provides for comfort and reliable long term attachment and also for maintaining the contact of the electrodes and sealing ribs with the skin as the skin
10 and muscle beneath, flex.

US Patent No. 4,004,578 discloses an expendable electro-cardiograph electrode comprising a thin metallic carrier member coated on the surface to be applied to the skin with an adhesive and having a plurality of metallic contact spikes projecting from the coated surface which spikes are devised to penetrate into
15 the skin. The coated and spiked surface is covered by at least one pull-off foil protecting same together with the spikes against environmental influences. On the carrier member, a transverse upwardly directed flange is provided for attachment to an electrocardiographic apparatus.

US Patent No. 5,305,746 discloses a disposable, pre-gelled, self-prepping
20 electrode having an array or mat of flexile tines which serve to part the high impedance outer layers of skin to expose the low impedance, blood enriched layers without scratching or abrading. The tines are preferably imbedded in a conductive gel layer. In an alternative embodiment, a self prepping layer of flexile tines embedded in gel may be a single disposable self-prepping layer that is mounted
25 over a permanent electrode.

It thus emerges that the prior art relates to disposable electrodes that are flexible but that the issues of compactness and especially the ability to fold the electrode are not addressed in the prior art.

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SUMMARY OF THE INVENTION

It is an object of the invention to provide a portable compact electrode assembly for a portable ECG monitor allowing standard twelve-lead ECG measurements to be carried out.

5 This objective is realized in accordance with a broad aspect of the invention by means of an electrode assembly for a portable ECG signaling device, comprising:

a thin, flexible electrode support supporting thereon a plurality of electrodes in spaced relationship;

10 CHARACTERIZED IN THAT:

the electrodes are configured for producing a twelve-lead electrocardiogram, and

the electrode assembly is foldable into a compact assembly when not in use.

According to a preferred embodiment, the electrode assembly is coupled to
15 an ECG transmitter embedded with a wallet and having controls accessible from inside the wallet. Such a wallet is provided with pockets for accommodating therein cash, credit cards and so on in known manner so that the patient who carries it is psychologically immune from the uncomfortable thought that anything medical is associated therewith.

20 In order to allow the patient to relay the ECG signal to a remote monitoring unit, a vocalizing unit may be provided for converting the ECG signal to a representative acoustic signal that can be sent over the telephone to the monitoring unit. Alternatively, the ECG signal may be modulated on to an r.f. carrier signal for direct transmission with the monitoring unit, thus not requiring that the patient be in
25 ready access with a telephone.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

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Fig. 1 shows pictorially an ECG electrode assembly according to the invention embedded within a wallet;

Fig. 2 shows pictorially the ECG assembly when in use;

Figs. 3 and 4 are block diagrams of alternative embodiments showing functionally the principal components in an ECG signaling device utilizing the ECG electrode assembly shown in Figs. 1 and 2; and

Fig. 5 is a pictorial representation of a wallet having integrally embedded therein an ECG signaling device according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

10 Fig. 1 shows pictorially a portable compact electrode assembly depicted generally as 10 comprising a thin, flexible electrode support 11 adapted to produce a 12-lead electrocardiogram in a manner similar to that shown in U.S. Patent No. 5,339,823. The flexible support 11 comprises a first, rectangular section 12 abutting a second, rectangular section 13 on one side thereof and, on an opposite side thereof, a serpentine strip 14 supporting an electrode RA. A lower edge of the first
15 rectangular section 12 abuts a third rectangular section 15, which in turn abuts at a lower edge thereof a fourth rectangular section 16. The fourth rectangular section 16 abuts at a first side edge thereof a serpentine strip 17 supporting an electrode LL and abuts at a second, opposing side edge thereof a substantially trapezoidal section
20 18. Contiguous sections may be folded along their common edges, shown dotted in the figure. By such means, the electrode support can be folded into a compact unit that can easily be accommodated inside a wallet 19. Specifically, the serpentine strip 17 and the trapezoidal section 18 are folded inwards along their respective fold lines so as to lie flat on the fourth rectangular section 16. Likewise, the
25 serpentine section 14 is folded along its fold line so as to lie flat on the first rectangular section 12. The fourth rectangular section 16 is then folded inwardly along its fold line so as to lie flat on the third rectangular section 15 which is likewise folded inwardly so as to lie flat on the first rectangular section 12. This

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having been done, the second rectangular section 13 is folded inwardly on to the now packed second, third and fourth rectangular sections including the adjoining serpentine strips 14 and 17 and the trapezoidal section 18. The first rectangular section 12 is provided with a slot 20, which is so located as to remain exposed even when the serpentine section 14 is folded and accommodates a flap 21 adjoining a side edge of the second rectangular section 13. By such means, the electrode unit 10 may be folded into a compact unit and the flap 21 tucked into the slot 20 so as to prevent the folded electrode unit from opening. The electrode unit 10 may then be carried separately in a person's pocket, for example, or, as noted above, may be accommodated within a wallet so as to provide further protection and ready accessibility. A ribbon connector 22 is attached to the electrodes for removably connecting to the electrode assembly 10 an electronic circuit described below with reference to Figs. 3 and 4 of the drawings.

ECG leads on the various sections of the electrode unit 11 are referenced by their universally adopted symbols V_1 , V_2 , V_3 , V_4 , V_5 and V_6 , LA, RA and LL. The electrodes are screen-printed on to the electrode support 11, although any other suitable method for fixing the electrodes to a flexible, insulating liner may be used.

Fig. 2 shows how the electrode assembly 10 is used for the determination of a full twelve-electrode ECG measurement. A patient 25 unfolds the electrode support 11 and affixes the second rectangular section 13 against his or her chest so that the leads V_1 and V_2 are substantially symmetrically disposed about his or her vertebrae. To this end, there are provided on each of the leads an electrically conductive, adhesive gel (not shown) which may, if desired, be covered with a wax liner that may be peeled off before use. The gel is specifically formulated to adhere to the patient's skin and to provide good electrical connection whilst allowing painless removal after use. Having affixed the two leads V_1 and V_2 , the four leads V_3 , V_4 , V_5 and V_6 are now disposed on the patient's left rib cage, being mutually displaced by the required distance appropriate to the patient so that the six leads V_1 to V_6 serve as Wilson precordial electrodes. The dimensions of the electrode

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support 11 are such that for a given patient, the electrode LA fits under the patient's left armpit, whilst the serpentine electrode RA is fully extended so as to be held under the patient's right armpit. The serpentine lead LL is then stretched and fitted near the patient's waist, typically being held in place using adhesive gel or by a belt (not shown).

Fig. 3 shows functionally an ECG signaling device 30 according to a first embodiment, comprising an electrode assembly 31 including an electrode array, waist and right-arm electrodes. The electrode array is dimensioned for placement against a patient's bare chest and, to this end, electrode assemblies are provided being suitably dimensioned for patients of various sizes. Furthermore, owing to anatomical differences between men and women, different electrode assemblies are preferably supplied to men and women. The electrode assembly 31 is coupled to an ECG lead switching and weighting network 32 which permits the proper selection of electrodes as well as lead weighting to produce a sequential selection of I, II, III, AVR, AVL, AVF, V₁, V₂, V₃, V₄, V₅ and V₆ ECG leads. The output of the ECG lead switching and weighting network 32 is coupled to an amplifier 33, which in turn is coupled to a frequency modulator 34 for converting the analog ECG signal to a representative frequency signal typically centered around 1700 Hz and frequency modulated by the patient's ECG signal. The variable frequency voltage is fed to an audio amplifier 35 whose output is fed to a loudspeaker 36, which together constitute a vocalizing unit for converting the ECG signal to an equivalent acoustic signal, which may be fed over the telephone line to a remote monitoring unit (not shown). Alternatively, the ECG signal may be digitized and transmitted digitally.

The ECG signaling device 30 is powered by means of an internal 9 volt battery 37 connected to a power supply 38 via a normally open switch (not shown). Closing the switch thus connects a regulated battery voltage to the various components of the ECG signaling device 30 so that a modulated tone representative of an ECG rhythm strip is output by the loudspeaker 36 for so long as the pushbutton switch 39 is depressed. The battery 37 may be removably mounted in a

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casing of the ECG signaling device 30 so as to be replaceable, or they may be irremovable in which case the ECG signaling device 30 must be discarded when the battery 37 is spent. The power supply includes a voltage regulator for providing a regulated voltage for the analog and digital components within the ECG signaling device 30. In addition, there is provided a low battery sensor that is adapted to shut down the circuits should the battery voltage decrease to the point where the regulated voltage or the performance of the device might be adversely affected.

A timing and control logic module 39 is coupled to the power supply 38 and to the ECG lead switching and weighting network 32 and include hard-wired logic gates that provide for selection of the proper electrodes and the timing functions of the ECG signaling device 30. Coupled to the timing and control logic module 39 is an enclosure-mounted pushbutton switch 40, which permits the patient to transmit a rhythm strip and 12-lead ECG. All transmissions are internally timed and the pushbuttons are electronically "latched" after depression, to ensure a complete transmission even if the patient's finger slips off the button during transmission. The timing and control logic module 39 could be replaced by a suitably programmed microprocessor, such as contemplated by a digital circuit 41 connected to the ECG lead switching and weighting networks 32. The digital circuit 41 also allows for transmitting the acoustic data as an equivalent digital signal.

Fig. 4 shows functionally an ECG signaling device 50 according to a second embodiment. Those components that are common to the first embodiment are reference by identical reference numerals. The ECG signaling device 50 comprises an electrode assembly 51 including an electrode array, waist and right-arm electrodes. In this case, a uniform electrode assembly is provided having different electrode arrays, each being properly dimensioned for placement against the bare chest of a respective sized patient. Likewise, different electrode arrays are provided for men and women to account for anatomical differences between the sexes. The electrode assembly 51 is coupled to an ECG lead switching and weighting network

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32 which permits the proper selection of electrodes as well as lead weighting to produce a sequential selection of I, II, III, AVR, AVL, AVF, V₁, V₂, V₃, V₄, V₅ and V₆ ECG leads. The output of the ECG lead switching and weighting network 32 is coupled to an amplifier 33, which in turn is coupled to a frequency modulator 34 for converting the analog ECG signal to a representative frequency signal typically centered around 1700 Hz and frequency modulated by the patient's ECG signal. The variable frequency voltage is fed to an audio amplifier 35 whose output is fed to a loudspeaker 36, which together constitute a vocalizing unit for converting the ECG signal to an equivalent acoustic signal, which may be fed over the telephone line to a remote monitoring unit (not shown). Alternatively, digital communication techniques can be employed using a digital circuit 41 connected to the ECG lead switching and weighting networks 32.

In order to ensure selection of the correct electrode array, a precordial electrode selector 52 is coupled to the ECG lead switching and weighting network 32 and is responsive to a male/female selector switch 53. The precordial electrode selector 52 allows for proper selection of the appropriate precordial electrodes V₁, V₂, V₃, V₄, V₅ and V₆ depending on the specified sex of the patient as set by the selector switch 53. To accommodate different chest sizes, two electrode selection areas are provided in the battery compartment. Three jumper blocks are used to select the V₅ and V₆ electrodes for male and female patients. The male/female selector switch 53 permits the selection of either the male or female V₁ and V₂ electrodes sets as well as the corresponding pre-selection of V₄, V₅ and V₆. The same V₃ electrode is used for male and female patients, regardless of chest size.

The remaining components of the ECG signaling device 50 are identical to those of the ECG signaling device 30 described above with reference to Fig. 3. It is to be noted that the electrode assembly 51 of the second embodiment is designed to be used repeatedly whilst the electrode assembly 31 of the first embodiment may be disposable. Furthermore, providing different electrode arrays for different sized

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male and female patients obviates the need to print redundant electrodes on the electrode support 11 and reduces the surface area thereof.

The circuitry shown in Figs. 3 and 4 may be connected to the electrode assembly using a flat, ribbon cable connector connected to the ribbon connector 22 (shown in Fig. 1) or alternatively can be surface mounted using flexible circuit technology on the electrode support 11. This allows for the electrode assembly to be disconnected from the electronic circuit after use and discarded. Another possibility is to surface mount the components on two or more rigid PCBs which are then interconnected by a flexible circuit. This renders the ECG signaling device more compact and amenable to its being embedded within a wallet of normal size.

Referring to Fig. 5, there is shown a wallet 55 having integrally embedded therein the ECG signaling device 30, the loudspeaker 36 and the pushbutton switch 40 being sewn or otherwise fixed to an outer surface 56 thereof. An inside surface 57 of the wallet is provided in known manner with a plurality of pockets 58 for accommodating notes, credit cards and so on. The remaining circuitry is mounted on a flexible circuit board (not shown), which is secured between the outer and inner surfaces 56 and 57 of the wallet 55. The use of a flexible circuit board allows for the wallet 55 to be folded and subject to moderate deformation as may be applied when the wallet 55 is placed, for example, in a patient's rear trouser pocket and is thereby subject to deformation whenever the patient sits down. In use, the patient must place the electrode array in position and telephone a remote monitoring unit. Connection having been established, the patient now activates the device by depressing the pushbutton switch 40. As noted above, this produces an acoustic signal representative of the ECG rhythm strip and the acoustic signal is transmitted over the telephone line in the usual way.

It will be appreciated that modifications and variations may be effected to the preferred embodiments without departing from the invention.

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For example, it is clear that the carrier frequency used to convey acoustic data does not have to be 1700Hz. As noted, digital communication techniques can be employed instead of transmitting the acoustic data as an analog signal.

Likewise, other common household articles may be adapted to incorporate
5 therein the ECG signaling device or, indeed, other electronic devices so as to serve a dual purpose, thereby increasing the likelihood that their owner will wish to make use thereof. It will also be appreciated that it is immaterial whether the ECG electrodes are fixed to an interior or exterior surface of the wallet. It should further be noted that the electrode assembly may be a completely independent self-
10 contained unit.

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CLAIMS:

1. An electrode assembly (10) for a portable ECG signaling device, comprising.

a thin, flexible electrode support (11) supporting thereon a plurality of electrodes in spaced relationship;

CHARACTERIZED IN THAT:

the electrodes (V_1 , V_2 , V_3 , V_4 , V_5 and V_6 , LA, RA, LL) are configured for producing a twelve-lead electrocardiogram, and

the electrode assembly is foldable into a compact assembly when not in use.

2. The electrode assembly according to Claim 1, being a self-contained unit.

3. The electrode assembly according to Claim 1, being embedded within a wallet (19, 55).

4. The electrode assembly according to any one of Claims 1 to 3, wherein the flexible support (11) comprises a plurality of foldable sections (12, 13, 15), one of which (13) is provided with a flap (21) for tucking into a slot (20) in another one (12) of said sections, whereby the electrode assembly can be folded into a self-contained compact unit prior to use.

5. The electrode assembly according to Claim 4, wherein there is joined to at least one of the foldable sections (12) a serpentine strip (14) supporting thereon one of said electrodes (RA).

6. The electrode assembly according to any one of the preceding Claims, wherein the electrodes are formed by a screen-printing technique.

7. The electrode assembly according to any one of the preceding Claims, including a plurality of electrode arrays dimensioned for different sized patients.

8. The electrode assembly according to Claim 7, wherein some of said electrode arrays are for male use exclusively and others are for female use exclusively.

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9. The electrode assembly according to any one of the preceding claims, further including a connector (22) for removably connecting to the electrode assembly an electronic circuit.

10. The electrode assembly according to Claim 9, being adapted for one time use.

11. An ECG signaling device (30, 50) comprising an electrode assembly according to any one of the preceding Claims.

12. The device according to Claim 11, including a vocalizing unit (35, 36) for producing an acoustic signal representative of the patient's ECG.

13. The device according to Claim 11, including digital circuitry (41) for producing a digital signal representative of the patient's ECG.

14. The device according to Claim 11 or 12, being integrally embedded within a wallet (19, 55).

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AMENDED CLAIMS

[received by the International Bureau on 10 January 2001 (10.01.01);
original claim 1 amended; remaining claims unchanged (1 page)]

1. An electrode assembly (10) for a portable ECG signaling device, comprising.

a thin, flexible electrode support (11) supporting a plurality of electrodes
5 (V1, V2, V3, V4, V5 and V6, LA, RA, LL);
characterized in that:

at least some of the electrodes (V1, V2, V3, V4, V5 and V6) are
constructed on the electrode support in proper spaced relationship for producing
electrical contact with respective areas of a patient's chest for producing an electro-
10 cardiogram when the electrode assembly is placed directly against the patient's
chest.

2. The electrode assembly according to Claim 1, being a self-contained unit.

3. The electrode assembly according to Claim 1, being embedded within a
wallet (19, 55).

15 4. The electrode assembly according to any one of Claims 1 to 3, wherein the
flexible support (11) comprises a plurality of foldable sections (12, 13, 15), one of
which (13) is provided with a flap (21) for tucking into a slot (20) in another one
(12) of said sections, whereby the electrode assembly can be folded into a self-
contained compact unit prior to use.

20 5. The electrode assembly according to any one of the preceding claims,
wherein there is joined to at least one of the foldable sections (12) a serpentine strip
(14) supporting thereon one of said electrodes (RA).

6. The electrode assembly according to any one of the preceding Claims,
wherein the electrodes are formed by a screen-printing technique.

25 7. The electrode assembly according to any one of the preceding Claims,
including a plurality of electrode arrays dimensioned for different sized patients.

8. The electrode assembly according to Claim 7, wherein some of said
electrode arrays are for male use exclusively and others are for female use
exclusively.

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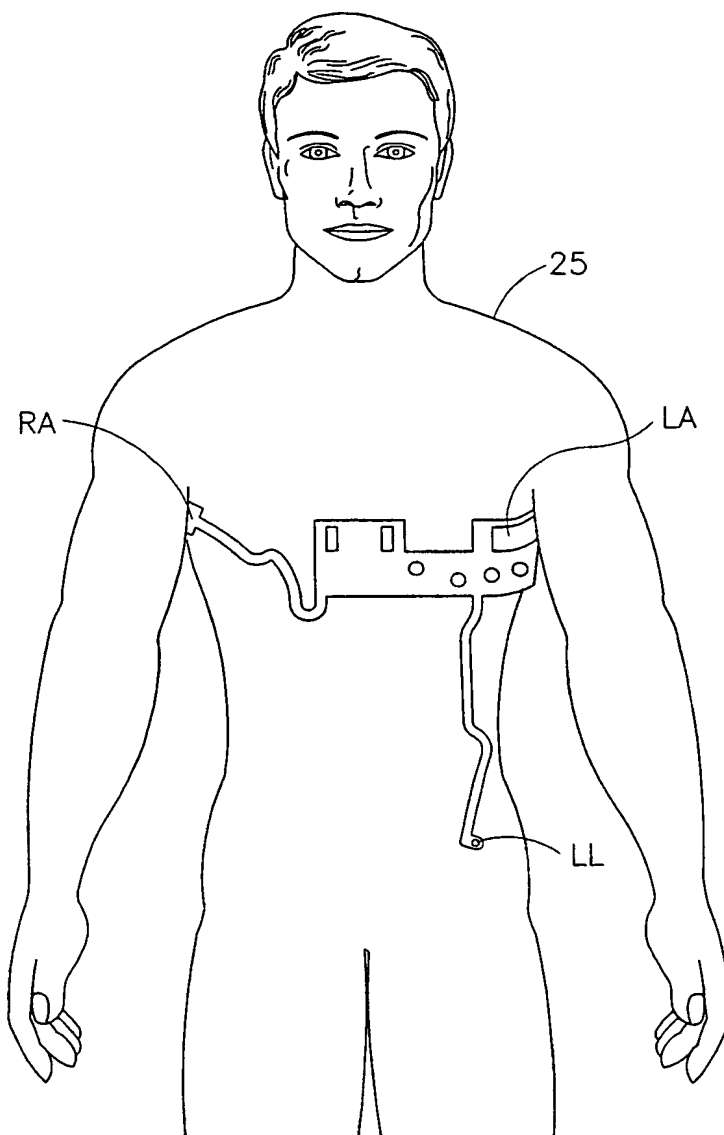


FIG.2

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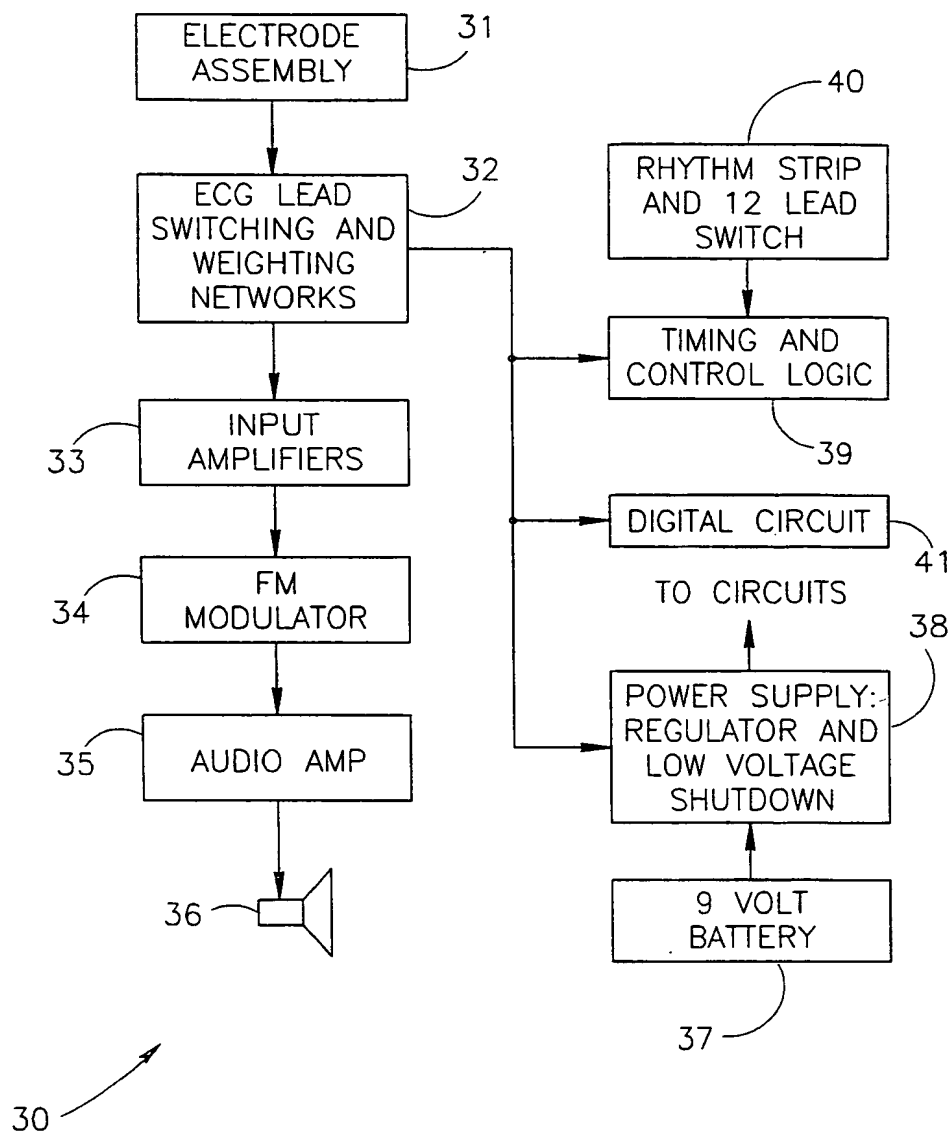


FIG.3

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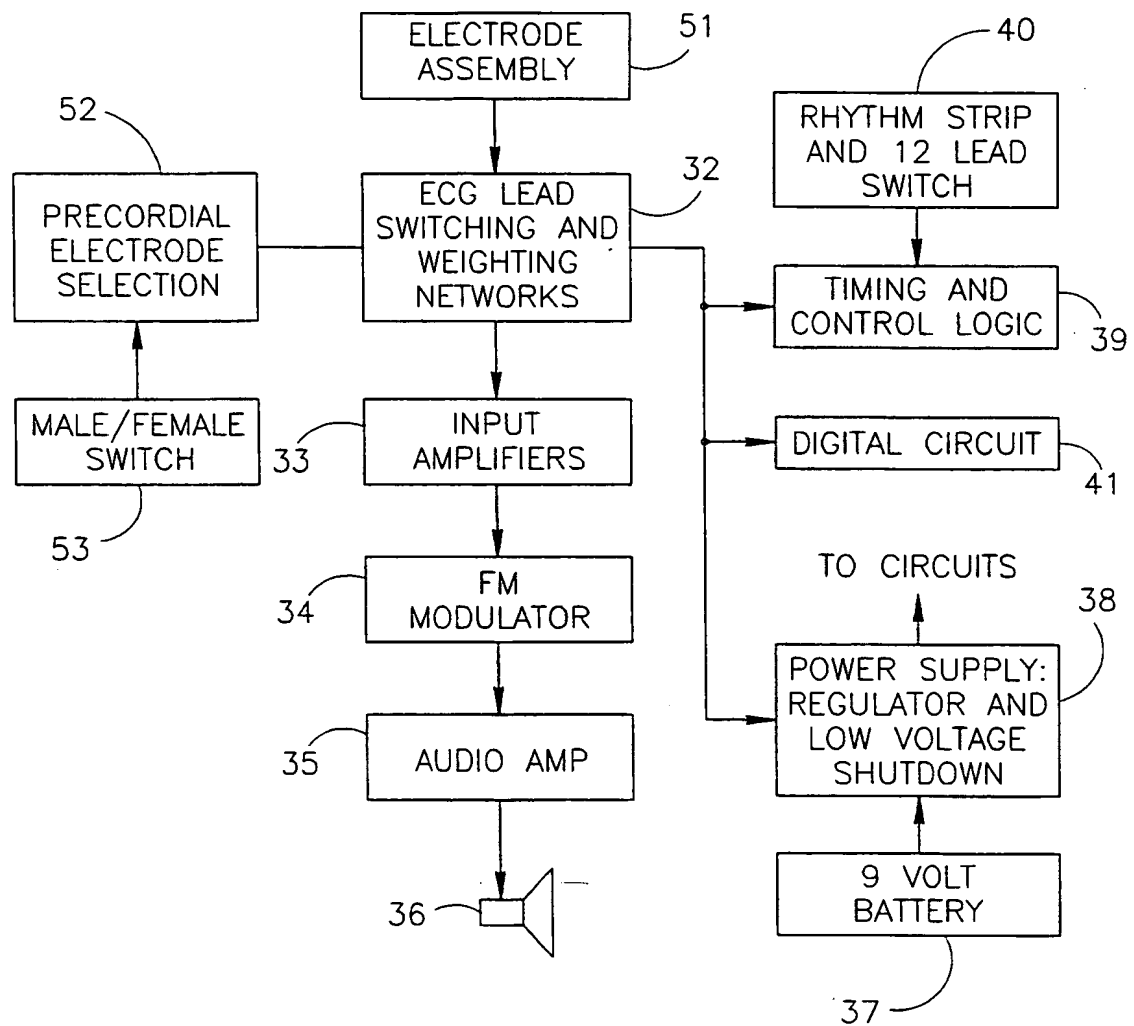


FIG. 4

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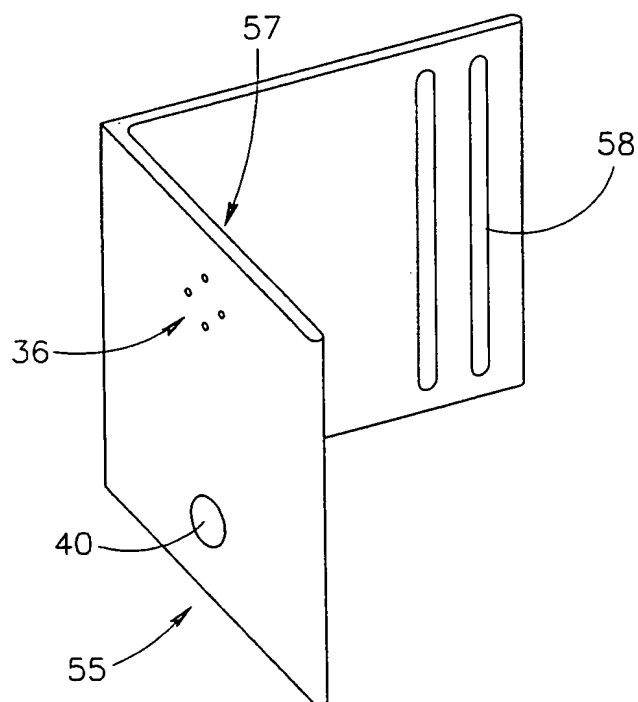


FIG. 5